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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/419,901 | 10/18/1999 | JENNIFER E. VAN EYK | 1997-023-04U | 2043 |

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| EXAMINER | |
|---|---|
| COOK, LISA V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/419,901 | VAN EYK ET AL. | |
| | Examiner | Art Unit | |
| | Lisa V. Cook | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,15-28,31,34,35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15-28,31,34,35 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry*

1. Applicants' response to the Office Action mailed August 26, 2003 is acknowledged. In response to the amendment filed therein claims 2-7, 19-21, 28, 35, and 37-41 were modified. Currently claims 1-7, 15-28, 31, 34-35, and 37-41 are pending and under consideration.

2. Objections and Rejections of record in paper #25 not reiterated below have been withdrawn.

REJECTIONS MAINTAINED

### *Double Patenting*

3. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7, 15-28, 31, and 34-35, and 37-41 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/115,589. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to the assessment of muscle damage in a subject via the detection of myofilament protein modification products. The instant claims require that one of the products be a chemical adduct of a myofilament protein. This invention is encompassed in the claims of application number 09/115,589 wherein the claims read on any myofilament protein modification product (including chemical adducts).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-7, 15-28, 31 and 34-41 remain provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/115,589 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented.

This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

***Response to Arguments***

The rejection will be held in abeyance until one of the applications is allowed. If at that time the obviousness-type double patenting issue still exists, Applicants will file the appropriate terminal disclaimer(s). Accordingly the rejection is maintained.

*With respect to the art rejection presented below: The disclosure merely teaches the detection of TnI as it relates to muscle damage. The examiner takes TnI to be a protein meeting the limitations of a myofilament protein modification product being a chemical adduct of a myofilament protein. See disclosure page 1-lines 17-22, page 4-lines 5-8, page 30, and page 50. Accordingly in order to promote compact prosecution the following art rejection is applied.*

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 15, and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (W0 94/27156).

Wicks et al. measure troponin I in a complex sandwich assay having immobilized solid phases for the purpose of assaying irreversible cardiac damage from biological samples such as blood. Specifically two binding partners are utilized, one capable of binding to troponin I and one binding partner specific for the C subunit of the troponin complex. (pages 2-5). The test provides rapid and specific measurement of troponin I and is useful in confirming the diagnosis of myocardial damage.

***Response to Arguments***

Applicant contends that Wicks et al. do not teach the detection of chemical adducts as defined in the specification on page 14. This argument was carefully considered, but not found persuasive because the rejected claims under 102(b) above do not require the measurement of the chemical adduct. The claim reads on instances wherein the chemical adduct is "absent". The only required detection is a myofilament protein modification product. TnI meets this requirement as supported by Applicants disclosure on page 19 beginning at line 3, for example. Accordingly the rejection is maintained.

## *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

*The patent of Van Eyke et al. was employed as prior art because priority was not claimed to the patented invention. The patent also contains a different inventive entity.*

I. Claims 2-7, 17-28, 31, 33-35, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over being unpatentable over Wicks et al. (W0 94/27156) in view of Wicks et al. (US patent #5,834,220) and in further view of Van Eyk et al. (US patent #6,248,549).

Wicks et al. (W0 94/27156) is set forth above.

Wicks et al. (W0 94/27156) differs from the instant invention in not teaching an assessment of muscle damage employing the measurement of two different myofilament protein modification products.

However, Wicks et al. teach method for assaying for cardiac troponin I along with troponoin C. See abstract. The process and test system provide rapid and specific measurements of troponin I and is highly suitable for confirming the diagnosis of myocardial damage (reading on muscle damage).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products (troponin I and troponin C) in muscle damage as taught by Wicks et al. in the method of Wicks et al. (W0 94/27156) involving troponin I analysis because Wicks et al. taught that Troponin I is one of three subunits of the troponin complex.

The other two subunits (designated T and C) are also immobilized on the thin myofilaments along with troponin I in both cardiac and skeletal muscle tissue. Column 1., lines 23-40. The utility of both troponin I and troponin C allowed for further distinction between cardiac muscle damage or skeletal muscles damage. See column 2, lines 37-49.

One having ordinary skill in the art would have been motivated to do this to acquire the enhanced sensitivity and ability to reduce false positives while providing more data sets for analysis, wherein accurate and precise detection is available.

Please see Wicks et al. (W0 94/27156) in view of Wicks et al. as set forth above.

Wicks et al. (W0 94/27156) in view of Wicks et al. differ from the instant invention in not teaching an assessment of muscle damage employing two different myofilament protein modification products from different proteins involving phosphorylation.

However, Van Eyk et al. teach method for assaying for muscle damage (contractile state). Including heart failure and myocardial stunning. See abstract. In one embodiment PAK kinase activity is assessed by measuring the phosphoryaltion of two different proteins (troponin I and calponin for example) see column 3, lines 30-39 and claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products from different protein with respect to their phosphorylation states (troponin I and Calponin) in muscle damage as taught by Van Eyk et al. in the method of Wicks et al. (W0 94/27156) in view of Wicks et al. to detect troponin I analysis because Van Eyk et al. taught that such method configurations allowed for the assessment of compositions in a screening format for their effect on PAK kinase activity or expression with respect to muscle disorders. See column 3, lines 1-39.

***Response to Arguments***

Applicant contends that the references do not teach one or more chemical adducts as an indication of muscle damage. Applicant further directs Examiner to page 14 of the specification for the definition of the chemical adduct. This argument was carefully considered but not found persuasive because the disclosure broadly reads on chemical adducts formed from phosphorylation of the myofilament proteins. This is taught by Van Eyk et al. Accordingly the rejection is maintained.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Chemical adducts that do not include covalent of two similar species) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. For reasons aforementioned, no claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

10. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Takahashi et al. (W0 96/10078) disclose methods for detecting myosin light chain 1 (MLC-1) as an indication of cardiac damage. The assay is conducted in biological sample like blood.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-0816.

Lisa V. Cook
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LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/19/04